HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

properly reviewed

D1453B

Refer to: CFN 1122788
98-BLT-36

BALTIMORE DISTRICT OFFICE
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

February 26, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John M. Brewer, President
Stellar Bio System, Inc.
9075 Guilford Road
Columbia, Maryland 21046

Dear Mr. Brewer:

A Food and Drug Administration (FDA) inspection conducted from January 15, 1998 to February 9, 1998 at your Columbia, Maryland facility determined that your firm manufactures Indirect Fluorescence Assay (IFA) products. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformity with Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997 by the Quality System Regulations. Since the records reviewed were dated before and after June 1, 1997, the deficiencies noted during the inspection were cross-referenced to the 1978 GMP and the CGMP requirements of the Quality System Regulations.

The deviations included the following:

1. Failure to specify a microbiological assurance level in the device master record for the indirect fluorescence assay kits produced using microbiologically controlled processes and/or components.

2. Failure to validate manufacturing processes such as steam autoclaving, dry heat sterilization, sterile filtration, and filling, including changes in standard operating procedures.

3. Failure to perform environmental monitoring of biosafety cabinets where microbiologically-controlled products are processed.

4. Failure to establish a specification for pre-filtration bioburden for positive and negative controls and conjugates that are specified as sterile for all IFA products.

5. Lack of a suitable reference standard thermometer capable of calibrating temperature monitoring equipment for dry heat ovens, refrigerators, freezers, and ultrafreezers (-70°C).

The letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and in the FDA-483 (enclosed) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may consider this information when considering the award of contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved, and no pre-market notifications (Section 510(k)s) will be found substantially equivalent for products manufactured at the facility in which the above CGMP violations were found until such violations have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge that you have submitted a response concerning our investigator's observations noted on form FDA-483. We are currently evaluating your response.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence and to comply with our request. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosure